RESmart ® CPAP System

User Manual

CE 0123

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Symbols

Control Buttons

Pressure Start / Stop

Ramp Start

Humidifier On / Off

User Button

User Button

Device

Attention, Consult Accompanying Documents

Type BF Applied part

Class II (Double Insulated)

AC Power

IPX1 Drip-Proof, Vertical

SN Serial Number of the product

Manufacturer

EC REP Authorised Reprisentative in the European Community

CE 0123 European CE Declaration of Conformity

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Intended Use

Intended Use

The RESmart system is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only.
The RESmart is to be used only on the instruction of a licensed health care professional. Your home care provider will make the correct pressure settings according to your health care professional's prescription.
Several accessories are available to make your OSA treatment with the RESmart CPAP system as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories.

IMPORTANT!

Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

- Bullous Lung Disease
- Bypassed Upper Airway
- Pneumothorax
- Pathologically Low Blood Pressure
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus. (Chest 1989; 96:1425-1426)
- The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of a sinus or middle ear infection.

Contact your health care professional if you have any questions concerning your therapy.

Specifications

Device Size

Dimensions: 220 × 194 × 112 mm, 313 × 194 × 112 mm (with InH2™ heated humidifier)

Weight: 1.6kg, 2.4 kg(with InH2™ heated humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5 to 30℃	-20 to 55℃
Humidity:	≤ 80% Non-condensing	≤ 93% Non-condensing
Atmospheric Pressure:	860 to 1060 hPa	500 to 1060 hPa

Mode of Operation

Continuous

AC Power Consumption

100 – 240V AC, 50/60Hz, 1.0A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IPX1 –Drip-Proof, Vertical

Pressure Range

4 to 20 hPa (in 0.5 hPa increments)

Pressure Stability

4 to 20 hPa (±1 hPa)

Altitude Compensation

Manually setting, level 0, 1, 2

Automatic altitude compensation

Sound Pressure Level

＜30 dB，when the device is working at the pressure of 10 hPa

Maximum Flow

Test Pressure(hPa)	4	8	12	16	20
Average flow at the patient connection port(L/min)	70.1	73.6	75.9	73.0	73.4

Warning & Cautions

CAUTION!

• This device is restricted to sale by or on the order of a physician.

WARNING!

Indicates the possibility for injury to the user or the operator.

• The instructions in this manual are not intended to supersede established medical protocols.

• This device is intended for adult use only.

• This device is not intended for life support.

• CPAP devices have the potential to allow rebreathing of exhaled air.
To reduce this potential, observe the following:
- Use BMC circuit accessories.
- Do not wear the mask and headgear for more than a few minutes while the device is not operating.
- Do not block or try to seal the vent holes in the exhalation port.
As with most CPAP devices: At low CPAP pressures, some exhaled gas (CO_2) may remain in the mask and be rebreathed.

• Do not use this device if the room temperature is warmer than 86 ℉ (30 ℃).
If this device is used at room temperatures warmer than 86 ℉ (30 ℃), the temperature of the airflow may exceed 106 ℉ (41 ℃). This could cause irritation to your airway.

• This equipment is not suitable for use in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.

• If you notice any unexplained changes in the performance of the RESmart, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider.

• To avoid electrical shock, disconnect the power cord before cleaning. DO NOT immerse the device in any fluids.

• Contact your health care professional if symptoms of sleep apnea recur.

• Using the RESmart at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.

Warnings & Cautions/Unpacking the System

CAUTION!

Indicates the possibility of damage to the device.

- ***Tobacco smoke may cause tar build-up within the RESmart that may result in the RESmart malfunctioning.***
- ***The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.***

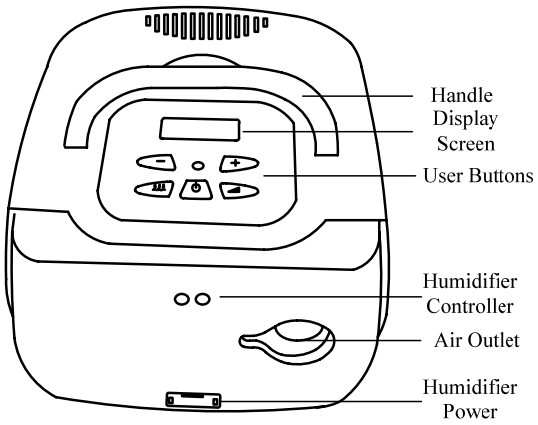
Additional warnings and cautions are located throughout this manual as they apply.

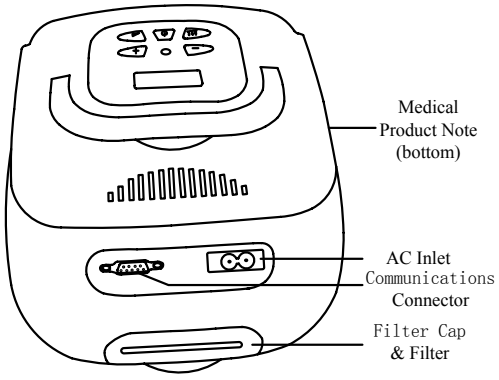
After unpacking the system, make sure you have everything shown here:

No.	Item	Num.
1	RESmart CPAP	1
2	Power Cord	1
3	Carrying Case	1
4	User Manual	1

IMPORTANT! ***If any of the above parts are missing, contact your home care provider.***

System Features





AC Inlet ..... Connect/disconnect the AC power cord here.

Air Outlet ..... Connect the flexible tubing (coaxial 22 mm) here.

Communications

Connector ..... For clinical use with the Data Management Software. Connect the communications cable here.

Display Screen ..... All system settings, total operating time, and therapy hours will appear here.

Filter Cap & Filters ..... The foam filter screens out normal household dust and pollens. The filter cap is designed to reduce the noise from the RESmart.

Humidifier Controller .... This controller turns the InH2 heated humidifier on/off and allows the heat setting to be adjusted. The humidifier is an optional accessory that may be purchased separately.

Humidifier Power ..... This socket provides the power to the InH2 heated humidifier.

Medical Product Note ..... For ease at airport security stations, there is a note on the bottom of the RESmart stating that it is medical equipment. It may help if you also take this manual with you when you travel.

User Buttons ..... These buttons can be used to turn on/off the system and change some of the system settings.

Handle ..... This handle is for lifting up the system.

First Time Setup

WARNING! ***Do not use the RESmart system until an appropriate professional adjusts the settings! To order any accessories not included with this system, contact your home care provider.***

Note to home care provider: Before beginning setup, be sure that you have available the RESmart Home Care Provider Setup Instructions. Setup instructions are not provided in this manual.

WARNING! ***DO NOT connect any equipment to the RESmart unless recommended by BMC or your health care provider.***

CAUTION! ***If the RESmart has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.***

First Time Setup (cont.)

Installing the Filter

1. Install the filters and filter cap.

CAUTION! ***The foam filter must be in place at all times when the RESmart is operating.***

a. Place the foam filter into the filter area on the back of the RESmart.

b. Attach the filter cap. Position the cap so that the small opening on the cap is facing down. Insert the cap's tabs into the filter area opening.

Power Cord

2. Connect the power cord. Plug the socket end of the power cord into the AC inlet on the back of the RESmart. Plug the pronged end of the power cord into an electrical outlet. System status will appear on the RESmart screen.

IMPORTANT! ***To remove AC power, disconnect the power cord from the electrical outlet.***

WARNING! ***Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.***

WARNING! ***The RESmart is powered on for use when the power cord is connected. The pressure start/stop button turns the blower on/off.***

3. Place the RESmart on a firm, flat surface.

CAUTION! ***Make sure the RESmart is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).*** *Also make sure that bedding, curtains, or other items are not blocking the filter or vents of the device. Air must flow freely around the device for the system to work properly.*

First Time Setup (cont.)

Device Settings

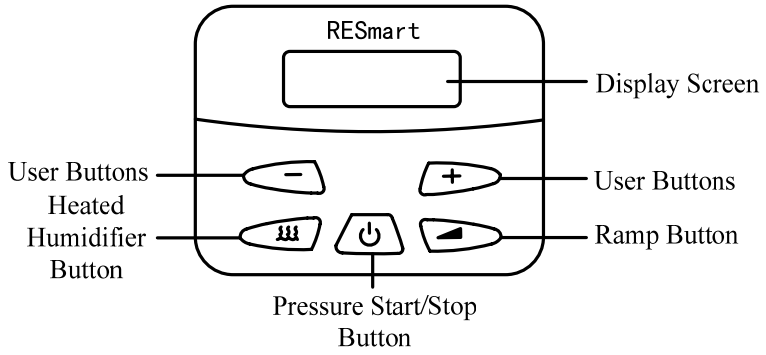
Display Screen: All device settings will appear here.

Pressure Start/Stop Button: Use this button to start/stop the airflow. DO NOT start the airflow until the circuit tubing is connected.

Heated Humidifier Button: Use this button when the optional InH2™ Heated Humidifier has been prescribed. This button will control the optional heated humidifier's output. Follow the instructions of the humidifier.

Ramp Button: When the airflow is turned on, use this button to restart the ramp cycle (which lowers the airflow pressure and then gradually increases it). This will allow you to fall asleep more comfortably. When the airflow is turned off, use this button to access the patient menu.
Note: The ramp feature is not prescribed for all users.

User Buttons: These buttons can be used when entering various menus to change some of the RESmart settings.

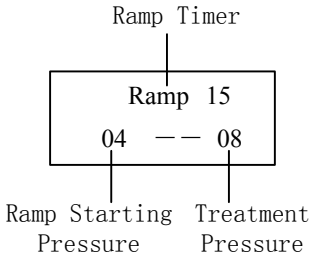


IMPORTANT! ***In the Setup Menu, the +/- user buttons are used to go to the previous/next question or setting and operate as up and down keys to change the settings, the ramp button is used to confirm the setting change, and the start/stop button will allow you to exit the Setup Menu without saving.***

First Time Setup (cont.)

Standby

4. After power on, system status will appear on display screen as below.



Ramp Starting Pressure: The starting pressure after blower is turned on. Default setting is 4hPa.

Treatment Pressure: The prescription pressure after ramp time. Default setting is 8hPa.

Ramp Timer: The ramp time from starting pressure to prescription pressure. Default setting is 15 minutes.

Device Settings

5. Verify/Change the RESmart settings. To start the setup menu, press and hold the ramp button until the setup menu appear (about 5 seconds) when system standby. (The airflow must be turned OFF.)

IMPORTANT! ***Pressing the ramp button (when the airflow is turned on) will lower the airflow pressure, if prescribed, and then will gradually increase it.***

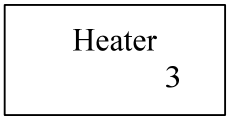
WARNING! ***DO NOT use the RESmart if the display is erratic. Contact your home care provider for further instructions.***

IMPORTANT! ***If at any time you wish to exit the setup menu, press the Pressure Start/Stop Button and the display will go back to the system standby screen.***

First Time Setup (cont.)

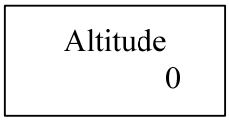
Setting the Humidifier a. When the optional InH2™ Heated Humidifier is used, this setting can change the temperature and humidity of airflow between level 0 to 5. Default setting is 3.

IMPORTANT! ***Press the Ramp Button to enter change status and press +/- User Buttons to change the setting. Press Ramp Button again to confirm the setting.***
Press +/- User Buttons to access the next setting.



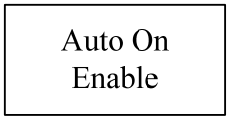
Setting the Altitude b. The altitude setting can be changed between level 0 to 2. Default setting is 0.

0 = less than 2,460 ft. (<750 m)
1 = 2,460 to 4,921 ft. (750 m to 1500 m)
2 = 4,924 to 8,202 ft. (1501 m to 2500 m)
*over 8,202 ft. = The airflow pressure may not be accurate. Contact your home care provider to have your pressure setting adjusted.



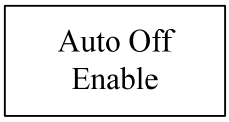
IMPORTANT! ***RESmart is already with automatic altitude compensation. Even if without setting the altitude, RESmart still can deliver proper pressure in any altitude worldwide.***

Setting Auto ON c. When the RESmart is standby and wearing mask, your deep breath will start airflow automatically. *(This function is **NOT** available on certain model.)* Default setting is Enable.



Setting Auto Off d. When the mask is removed, the RESmart will stop airflow automatically. *(This function is **NOT** available on certain model.)* Default setting is Enable.

First Time Setup (cont.)

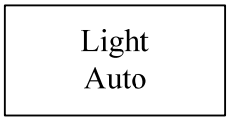


Setting the LCD Light e. This setting allows you to adjust the LCD light among Auto, On and Off. Default setting is Auto.

Auto: LCD light will be turned on when any button pressing and turned off after few seconds.

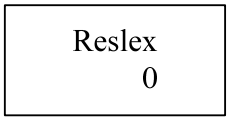
On: LCD light will be turned ON always.

Off: LCD light will be turned OFF always.



Setting the Alert f. This setting allows you to turn on/off the patient disconnect Alert. When a large, continuous air leak (such as mask removal) has been detected in the circuit, this setting enables/disables the audible alert (a beeping sound). This setting is only effective when the Auto Off setting is disabled. *(This function is **NOT** available on certain model.)* Default setting is Disable.

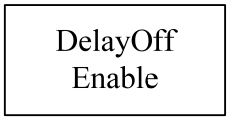
Setting the Reslex g. The Reslex setting displays the Reslex level set by your home care provider. This setting allows you to adjust the level of air pressure relief that you feel when you exhale during therapy. Your home care provider will have already set a Reslex level. If this is not comfortable for you, you can increase or decrease the setting. The setting of "1" provides a small amount of pressure relief. To increase the pressure relief, change the setting to "2". *(This function is **NOT** available on certain model.)* Default setting is 0 (disable).



First Time Setup (cont.)

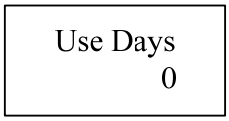
Setting the Delay Off

h. When the optional InH2™ Heated Humidifier is used, this setting allows the air flow continue for about 15 minutes at very low pressure (about 2hPa) after RESmart is turned off. This will blow off the left vapor and protect the RESmart. Default setting is Enable.



Use Days

i. The number of nights the RESmart was used for therapy for more than 4 hours will appear. This screen is only for reference. Your home care provider may periodically ask you for this information.



Exit the Settings

The settings are complete. Press the +/- user button to access the SAVE setting and Ramp Button to save all changes and exit the settings menu.

First Time Setup (cont.)

Assembling the Circuit

6. Assemble the circuit. To use the system, you will need the following accessories in order to assemble the recommended circuit.

• Nasal Mask with integrated exhalation port

• 6 ft. (1.83 m) flexible Tubing

• Headgear (for the mask)

WARNING!

If multiple persons are going to use the RESmart (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the RESmart and the circuit tubing. Pressures must be verified by your home care provider when alternate or optional accessories are in place.

a. Connect the flexible tubing to the air outlet on the front of the RESmart.

b. *If you are using a mask with a built-in exhalation port,* connect the mask's connector to the flexible tubing.

If you are using a mask with a separate exhalation port, connect the flexible tubing to the exhalation port. Position the exhalation port so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation port.

WARNING!

Do not block or otherwise try to seal the air openings (vent holes) on the exhalation port.

Explanation of the warning: The RESmart is intended to be used with masks and circuits that have an exhalation port designed to exhaust CO_2 from the circuit. When the RESmart is turned on and functioning properly, new air from the RESmart flushes the exhaled air out through the exhalation port. When the RESmart is turned off, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This warning applies to most CPAP devices.

WARNING!

If you are using a full face mask (i.e., a mask covering both your mouth and your nose), the mask must be equipped with a safety (entrainment) valve.

Accessories

Contact your home care provider for additional information on the accessories available for the RESmart system. When using optional accessories, always follow the instructions enclosed with the accessories.

Adding a Humidifier

The InH2™ Heated Humidifier is available from your home care provider. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow.

WARNING!

The RESmart unit should only be connected to the humidifiers or cacessories specified in this Manual. Connection of other Items may result in injury,or damage to the RESmart unit.

Adding Oxygen

Oxygen may be added at the mask connection. Please note the warnings listed below when using oxygen with the RESmart.

WARNING!

The oxygen supply must comply with the local regulations for medical oxygen.

WARNING!

Turn the RESmart on before turning the oxygen on. Turn the oxygen off before turning the RESmart off.

Explanation of Warning: ***When the RESmart is turned off, but the oxygen flow is still turned on, oxygen may accumulate within the RESmart enclosure and create a fire risk. Turning the oxygen off before turning the RESmart off will prevent oxygen accumulation in the RESmart and will reduce the risk of fire. This warning applies to most CPAP devices.***

WARNING!

Oxygen accelerates fires. Keep the RESmart and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. DO NOT smoke in the area near the RESmart or the oxygen container.

Routine Use

Connecting the Circuit

1. Connect the circuit.

IMPORTANT!

Before each use, examine the flexible tubing for any damage or debris. If necessary, clean the tubing to remove the debris. Replace any damaged tubing.

a. Connect the mask to the headgear, following the instructions included with the headgear.

b. Put on the mask and headgear, and breathe normally through your nose. The airflow should automatically start when you begin breathing through the circuit. If the airflow does not start within four breaths, press the pressure start/stop button on the top of the RESmart. When operating the system with some mask types or some circuit configurations, the airflow may NOT automatically start.

Adjusting the Circuit

2. Adjust the circuit. Lie down on your bed, and adjust the flexible tubing so it is free to move if you turn in your sleep. Adjust the mask and headgear until you have a comfortable fit and there are no airflow leaks into your eyes.

Using the Ramp Button

Pressing the ramp button will reduce the air pressure when you are trying to fall asleep. The air pressure will gradually increase until your prescription pressure is reached. If your physician prescribed ramp for you, pressing the button will reduce the pressure and then gradually increase (ramp) the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably. *Note: The ramp feature is not prescribed for all users.*

3. Press the Ramp button on the top of the RESmart. You can use the Ramp button as often as you wish during the night.

Routine Use (cont.)

Turning the System OFF

4. Remove the mask and headgear. Press the pressure start/stop button on the top of the RESmart to stop the airflow.
Or, if the Auto Off setting has been enable, the airflow will automatically turn off.

IMPORTANT!

The humidifier button is active only when an InH2 Heated Humidifier is connected or when the RESmart is in the Setup Menu. Refer to the InH2 Heated Humidifier's instructions for additional information.

Helpful Hints

• If the alert tone sounds, press any button on the RESmart to silence the alert tone. Refer to the "Troubleshooting" Section of the manual for further instructions.
• Make sure that bedding, curtains, or other items are not blocking the filter or vents of the RESmart. Air must flow freely around the RESmart for the system to work properly.
• If the airflow from the RESmart feels cold, reposition the circuit tubing so that it runs under your bed covers to reduce heat loss while you sleep.
• If interruption of the power supply occurs during system working, the audible alert (a beeping sound) will start and continue. Restoration of the power supply will stop the audible alert.
• After interruption and restoration of the power supply, the RESmart will resume with the working status before interruption automatically.

Routine Maintenance

Cleaning the Filter

The foam filter should be cleaned at least once every two weeks under normal usage and replaced with a new one every six months.

CAUTION!

Operating the RESmart with a dirty filter may keep the system from working properly and may cause damage to the device.

1. Remove the filter cap by gently pressing on its bottom.
2. Change the filter.
    a. Remove the foam filter by gently pulling around the edges of the filter. Rinse the filter in a steady stream of running water. Squeeze out the water and repeat. Air dry the filter on a rack for 8 to 12 hours or in a clothes dryer for 15 to 20 minutes.
    b. Insert the filter into the filter area on the back of the RESmart. Replace the filter cap.

CAUTION!

Never install a wet filter into the RESmart. We recommend that you clean the filter in the morning and alternate using the filter provided with the system to ensure enough drying time for the cleaned filter.

Cleaning the System

Clean the mask and tubing daily.

WARNING!

To avoid electrical shock, unplug the RESmart before cleaning. Do not immerse the RESmart in any fluids.

1. Disconnect the flexible tubing from the RESmart. Gently wash the flexible tubing in a solution of warm water and a mild detergent. Rinse the tubing thoroughly and air dry.
2. Wipe the outside of the RESmart with a cloth slightly dampened with water and a mild detergent. Let the RESmart dry before plugging in the power cord.
3. Inspect the RESmart and all circuit parts for any damage after cleaning. Replace any damaged parts.
4. For details on cleaning your mask and accessories, refer to the cleaning instructions packaged with the accessories.

Reordering/Service/Traveling with the System

Reordering

Contact your home care provider to order accessories or Replacement filters.

Service

The RESmart system does not require routine servicing.

The RESmart unit contains electrical and/or electronic equipment. When necessary, dispose of the RESmart and accessories in accordance with local regulations.

WARNING!

If you notice any unexplained changes in the performance of the RESmart, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.

WARNING!

If the RESmart malfunctions, contact your home care provider immediately. Never attempt to open the RESmart's enclosure. Repairs and adjustments must be performed by BMC authorized service personnel only.
Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
If necessary, contact your local authorized dealer or BMC MEDICAL CO., Ltd. for technical support and documents.

Traveling with RESmart

When you are traveling, the carrying case is for carry-on luggage only. The carrying case will not protect the system if it is stored as checked baggage.

Security Stations

For convenience at security stations, there is a note on the bottom of the RESmart stating that it is medical equipment.
It may be helpful to bring this manual along with you to help security personnel understand the RESmart.

Checking the Power Cord

If you are traveling to a country with a line voltage different than the one you are currently using, a different power cord or an international plug adapter may be required to make your power cord compatible with the power outlets of the country to which you are traveling. Contact your home care provider for additional information.

Troubleshooting

The table below lists common problems you may have with the RESmart system and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

Problem	Solution(s)
The pressure being delivered feels different.	Check the altitude setting to be sure it is set to your altitude. Change the altitude setting if necessary. If the altitude setting is correct, contact your home care provider for directions on having the RESmart serviced. Please have the device's serial number ready when you call.
The airflow from the RESmart seems warm.	Replace or clean the filter. Make sure the RESmart is away from bedding or curtains that could block the flow of air around the RESmart. Make sure the RESmart is away from heating equipment (e.g., forced air vents, radiators).
The noise level of the RESmart has changed to include unusual or harsh sounds during operation.	Contact your home care provider for directions on having the RESmart serviced. Please have the device's serial number ready when you call.
The RESmart will not turn on.	Make sure that the RESmart is plugged into a working outlet. Contact your home care provider for directions on having the RESmart serviced. Please have the device's serial number ready when you call.
Pressing the ramp button does not reduce the air pressure.	Contact your home care provider. Ramp may not have been prescribed for you.
The RESmart has been dropped into water or fluids have gotten into the enclosure.	Discontinue use. Disconnect the power cord from the AC wall outlet. Contact your home care provider for directions on having the RESmart serviced. Please have the device's serial number ready when you call.

EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The RESmart is intended for use in the electromagnetic environment specified below. The user of the RESmart should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1, Class B	The RESmart uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1, Class B	The RESmart is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Class D	

Guidance and manufacturer's declaration - electromagnetic immunity

The RESmart is intended for use in the electromagnetic environment specified below. The user of the RESmart should make sure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95 % dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RESmart requires continued operation during power mains interruptions, it is recommended that the RESmart be powered from an uninterruptible power supply or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 A/m	If the pressure deviates more than is indicated in the device specification, it may be necessary to position the RESmart further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.

NOTE: U_T is the AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The RESmart is intended for use in the electromagnetic environment specified below. The user of the RESmart should make sure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RESmart, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applied.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RESmart is used exceeds the applicable RF compliance level above, the RESmart should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RESmart.

[b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Limited Warranty

BMC MEDICAL CO., Ltd. warrants that the RESmart ® CPAP device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year for main unit and three (3) months for all accessories from the date of sale by BMC MEDICAL CO., Ltd. to the dealer. If the product fails to perform in accordance with the product specifications, BMC MEDICAL CO., Ltd. will repair or replace, at its option, the defective material or part. BMC MEDICAL CO., Ltd. will pay customary freight charges from BMC MEDICAL CO., Ltd. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

BMC MEDICAL CO., LTD. DISCLAIMS ALL LIABILITY FOR ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY SALE OR USE OF THIS PRODUCT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

To exercise your rights under this warranty, contact your local, authorized dealers or:

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